

***Title: Gastric Tissue Stapler Comparison Study  
Protocol Synopsis***

**Protocol Number: CP-2018-01**

**Principal Investigator: Aaron Hoffman MD, FACS**

**Sponsor: Standard Bariatrics**

**Revision: D**

***June 17, 2019***

## STATEMENT OF COMPLIANCE

The clinical study will be conducted according to the International Conference on Harmonization Good Clinical Practice (ICH GCP), which is applied to the United States (US) Code of Federal Regulations (CFR). A guarantee will be provided by Principal Investigator that the protocol will be conducted as written without deviations. The persons involved in conductance of this study understand ICH GCP Training and Human Subject Protection.

All study documents including protocol, recruitment materials, participant material and informed consent form(s) will be submitted to the IRB authority for review and approval. The consent form and approval letter will be obtained prior to enrollment of participants. Any modification in the protocol will be sent for review and approval by the IRB prior to any change implementation in the study. Any change to the consent form will be reviewed and approved by the IRB; if the changes to the informed consent are made, a determination will be made if new consent will be required from participants who were given previous approved consent.

## PROTOCOL SUMMARY

**Title:**

**Study Description:**

This study is conducted to compare performance characteristics of staple lines resecting the stomach in excised human gastric tissue with existing Echelon Flex Powered Plus GST System (Ethicon, size: 60mm, “Echelon”) stapler and the Titan SGS (Standard Bariatrics, “Titan”).

The Study is a single center clinical trial, randomized (1:1, Arm A - Ethicon Echelon 60 application, Arm B - Standard Bariatrics Titan SGS application) which utilizes the excised stomach tissue from up to 75 adults undergoing laparoscopic sleeve gastrectomy (LSG). This study will be conducted in the USA.

The following characteristics will be studied:

- 1) Burst pressure and burst location in the test specimen
- 2) Percentage of malformed staples

**Objectives:**

Primary Objective:

To obtain comparative data between the Echelon Stapler and the Titan Stapler in excised human stomach tissue for the following parameters:

- 1) Burst pressure and burst location in the test specimen
- 2) Percentage of malformed staples in test staple line

Secondary Objectives:

The following data will also be recorded:

- 1) Tissue thickness and length along the original stomach resection line (i.e. measuring the length and thickness of the excised stomach specimen)
- 2) Staple height (average, range, SD)
- 3) Visual inspection and photographs of the staple lines
- 4) Number of consecutive staple malformations per length of staple line; type of malform at each location and likelihood of leak path development.

**Study Population:**

This is an observational, non-intervention study. Only excised tissue will be tested. This study will include resected stomachs from the following population:

Inclusion criteria:

1. Laparoscopic sleeve gastrectomy patients at study site, ages 18 to 80

Exclusion criteria:

1. Prior gastric surgery (lap band, Nissen fundoplication, G tube, greater curve plication, etc.)
2. Gastric lesion recognized during surgery (entire specimen would be sent to pathology)
3. Stomach damaged during extraction

**Description of Sites  
Enrolling Participants:**

1 site (USA), up to 75 subjects

**Description of Study:**

Both groups of the randomized trial will utilize the excised stomach (specimen) from patients of LSG. The specimen will be removed in a manner to preserve tissue integrity as described in the protocol.

The specimen will be immediately transferred to the onsite laboratory for examination and one additional resection with either the Echelon 60 mm stapler (Arm A) or the Titan stapler (Arm B).

The specimen will first be examined for tissue integrity. If undamaged, the specimen will be measured and the length and thickness of the existing cut line on the specimen will be recorded using the Tissue Measuring Device (TMD).

The test resection line will be placed 2 cm from the existing staple line with either the Echelon stapler (Arm A) or the Standard Bariatrics Titan SGS (Arm B). If Arm A, Echelon staple cartridges will be selected based on tissue thickness. After the resection of tissue is made, the following assessments will be conducted:

- Visual inspection and photographs of the staple lines
- Burst pressure and burst location will be assessed in the specimen with one staple line (i.e. the test staple line) with a pressure volume curve recorded.
- The two-sided staple line specimen will be sent to an independent laboratory (Kinetic Vision, Cincinnati, OH) for imaging. Percentage of malformed staples in test staple line will be recorded by an independent assessor. Consecutive staple malformations will be recorded by the independent assessor. Well-formed staples will be measured and location cataloged.

**Study Duration:** Q1 2019 to Q3 2019 (up to 39 weeks)

**Participant Duration:** The patient-related activities of the trial are limited in duration and scope:

- Screening for eligibility for enrolment (up to 2 visits over a maximum of 3 weeks) and consent
- Removal of specimen during surgical procedure

The remainder of study activities are conducted on the excised specimen and do not require subject involvement.